ONWARD® Medical Reports Full Year 2023 Financial and Operating Results and Shares 2024 Highlights Year-to-Date

Submitted FDA De Novo application for ARC-EX® System

Successfully raised EUR 20M in equity capital

Announced positive top-line results from Up-LIFT pivotal study

Forged partnership to provide rapid access to US Veterans Health Administration

Continued to pioneer brain-computer interface therapies for SCI

EINDHOVEN, the Netherlands — April 25, 2024 — ONWARD Medical N.V. (Euronext: ONWD), a medical technology company creating innovative spinal cord stimulation therapies to restore movement, function, and independence in people with spinal cord injury (SCI), today announces its Full Year 2023 Financial and Operating Results.

"In 2023, we made substantial progress against our objectives and laid the foundation to bring our ARC-EX System to the US market later this year," said Dave Marver, CEO of ONWARD Medical. "We are off to a strong start again in 2024, raising EUR 20M in equity capital and submitting our De Novo application to the FDA for the ARC-EX System."

Full Year 2023 and Early 2024 Highlights

Clinical and Development:

- In April 2023 at the American Academy of Neurology Annual Meeting, neurosurgeon Dr. James Guest of the University of Miami and the Miami Project to Cure Paralysis shared that in addition to meeting all primary safety and effectiveness endpoints, the Up-LIFT pivotal study demonstrated that 72% of participants responded to ARC-EX Therapy[1].

- In May 2023, *Nature* published on the progress of a participant from a 2021 clinical feasibility study in which the Company's ARC-IM® Therapy was paired with an implanted brain-computer interface (BCI) for the first time, resulting in that individual gaining augmented control over when and how he moved his paralyzed legs. In August 2023, the Company also completed the successful first-in-human use of an implanted BCI paired with the ARC-IM System to help a person with SCI recover thought-driven movement in his arms and hands. The Company calls this combined platform that enables thought-driven movement the "ARC-BCI™ System."

- Also in May 2023, the Company completed the successful first-in-human use of the ARC-IM Lead, designed to deliver ARC Therapy to areas of the spinal cord responsible for a specific function, such as mobility or blood pressure regulation. The Company is

[1] Responder defined as a participant who met or exceeded the minimally important difference (MID) criteria for at least one outcome of the strength domain and at least one outcome of the functional performance domain. Responders had an average time since injury of 6 years, with a range of 1-34 years.

developing a portfolio of ARC-IM Leads, each optimized for placement on a different area of the spinal cord.

- In September 2023, the Company expanded its HemON clinical feasibility study to explore use of the ARC-IM System to improve blood pressure regulation after SCI with the addition of Sint Maartenskliniek in the Netherlands. This additional research site prepares the Company for expected Q4 2024 initiation of a global pivotal trial called Empower BP to assess the safety and efficacy of ARC-IM Therapy to improve blood pressure regulation.

- In November 2023, the Company announced a publication in *Nature Medicine* highlighting the potential for ARC-IM Therapy to address gait challenges related to Parkinson's disease. Also in November, ONWARD Medical research partner .NeuroRestore was awarded a $1 million grant from The Michael J. Fox Foundation for Parkinson's Research (MJFF) to implant the Company's ARC-IM System and investigate the impact of ARC-IM Therapy in six additional participants with Parkinson's disease.

- In 2023, the Company was awarded five new Breakthrough Device Designations (BDDs) by the US Food & Drug Administration (FDA) for its ARC Therapy platforms, bringing the Company's total number of BDDs to 9. A 10th BDD was added for ARC-BCI in February 2024.

- In March 2024, ONWARD was only the second BCI company admitted into the FDA's new Total Product Lifecycle Advisory Program (TAP) for its brain-computer interface technology.

- In April 2024, the Company announced it had submitted a De Novo application to the US FDA to obtain regulatory clearance to begin marketing its non-invasive ARC-EX System in the United States. Clearance is expected Q4 2024.

Intellectual Property:

- The Company was issued more than 50 new patents during 2023, bringing its total number of issued patents to more than 240, further strengthening its first-mover advantage.

Commercial:

- In September, the Company announced a partnership with Lovell Government Services (Lovell), a Service-Disabled Veteran-Owned Small Business (SDVOSB). Lovell is a government vendor and third-party logistics provider partnering with more than one hundred US healthcare providers. The two-year distribution agreement gives the Company contract access to the United States Veterans Health Administration, the

world's largest healthcare system providing SCI care, and the US Department of Defense Military Health System, the world's largest military healthcare provider.

Corporate:

- In Q1, the Company strengthened its leadership team, appointing Erika Ross Ellison as Vice President, Global Clinical, Regulatory, and Quality, and Sarah Moore as Vice President, Global Marketing.

- In Q2, Bryan, Garnier & Co reinitiated research coverage of ONWARD Medical following the appointment of a new equity research analyst. In 2024, KBC Securities and Stifel both initiated research coverage of the Company. Equity research analysts from 5 investment banks now cover ONWARD, each with a Buy rating and target price at a substantial premium to the current share price.

- In Q3, Robert Odell joined the Company as Vice President of Operations. Robert was formerly President and Chief Operating Officer of Cardiac Insight, Inc. Prior to that, he served as COO of Cardiac Science Corporation, a publicly traded manufacturer of Class II and Class III medical devices.

Financial:

- The Company ended the year with net cash of EUR 29.8M (2022: EUR 61.8M).

- Management confirmed that with the gross proceeds of EUR 20.0M from the share capital increase in March 2024, the Company has a cash runway through mid-2025.

- For 2023, the Company reported an operating loss of EUR 35.5M compared to EUR 32.0M in 2022.

In EUR millions *For the twelve-month period ended December 31*	**2023**	**2022**
Total Revenues & Other Income	**0.5**	**2.1**
Total Operating Expenses	**(36.0)**	**(34.2)**
Operating Loss for the Period	**(35.5)**	**(32.0)**
Net Finance Expenses	(0.6)	(1.5)
Income Tax Expenses	(0.1)	0.8
Net Loss for the Period	**(36.2)**	**(32.8)**

At	**31 Dec. 2023**	**31 Dec. 2022**
Cash position at the end of the period	29.8	61.8
Interest Bearing Loans	(15.3)	(12.7)
Equity	17.9	52.6

Total Revenues & Other Income

- Other Income, mainly grant income, decreased to EUR 0.5M (2022: EUR 2.1M) mainly due to a change in recognition of grant income.

Total Operating Expenses

- Total Operating expenses increased during 2023 by EUR 1.8M to EUR 36.0M (2022: EUR 34.2M). Research & Development (including Clinical) expenses were stable at EUR 18.8M (2022: EUR 18.9M), mainly including costs to finalize all components of the ARC-EX platform for FDA submission. Marketing expenses increased from EUR 2.0M in 2022 to EUR 2.9M driven by heightened market access activities in preparation for ARC-EX launch, including pricing studies and congress attendance to build awareness for the Company's therapies within the SCI Community. General and Administrative expenses increased by 7% up to EUR 11.3M in 2023 (2022: EUR 10.6M) mainly due to the strengthening of overall operational capabilities to prepare the launch of the Company's first commercial product.

Net Finance Expenses

- Net Finance expense decreased from EUR 1.5M in 2022 to EUR 0.6M in 2023 due to higher financial income related to interest earned from our positive cash balance in fixed term deposits. The financial expense is related to the interest expense on the Company's longstanding innovation loan from the Netherland Enterprise Agency (RVO).

Net Loss for the Period

- The Company realized a Net Loss for the period of EUR 36.2M versus EUR 32.8M in 2022 driven by the lower grant income and higher operating expenses.

Net Cash Position

- The Company ended the year 2023 with a net cash position of EUR 29.8M (2022: EUR 61.8M). Cash outflow from operating activities increased from EUR 26.7M in 2022 to EUR 32.3M in 2023 driven by the higher operating loss and changes in working capital. Cash flow from financing activities was EUR 0.8M positive (2022: EUR 0.6M negative) driven by proceeds from the RVO loan.

2024 Outlook

Innovation, Clinical and Regulatory Developments:

- On April 2nd, the Company announced it submitted a De Novo application for FDA clearance for the ARC-EX System, with an anticipated authorization to commercialize the platform in the US in the second half of 2024. The Company aims to apply for CE Mark and European authorization in 2025.

- Based on positive feedback from potential customers on the value of the ARC-EX System, now demonstrated to be the first-ever therapy to restore hand and arm function after chronic SCI, the Company anticipates an approximate list price of USD 30,000. In addition, the Company expects to supplement revenue by offering tiered service packages.

- The Company plans to apply for FDA IDE approval and to begin its global pivotal trial for the ARC-IM System, called Empower BP, in the second half of 2024 to provide the evidence necessary to ultimately submit a pre-market approval (PMA) application to the US Food and Drug Administration (FDA) and other global regulatory bodies.

- The Company intends to gain additional clinical data and experience with its implantable ARC-IM System in 2024, with several implants planned with support from the Michael J. Fox Foundation for Parkinson's Research and several ARC-IM System implants planned in combination with an implanted brain-computer interface (BCI) with support from the European Innovation Council. The Company calls this BCI-augmented system, ARC-BCI.

Corporate:

- At year-end 2023, the Company anticipated its cash position would fuel operations through the end of 2024. In March 2024, the Company completed a EUR 20M equity financing that strengthened its cash position to support investments in product development, clinical trials, operational and commercial capabilities, and extending its cash runway through mid-2025.

To learn more about ONWARD Medical's commitment to partnering with the SCI Community to develop innovative solutions for restoring movement, function, and independence after spinal cord injury, please visit ONWD.com.

**All ONWARD Medical devices and therapies, including but not limited to ARC-IM®, ARC-EX®, ARC-BCI™, and ARC Therapy™, alone or in combination with a brain-computer interface (BCI), are investigational and not available for commercial use.*

About ONWARD Medical

ONWARD® Medical is a medical technology company creating therapies to restore movement, function, and independence in people with spinal cord injury (SCI) and movement disabilities. Building on more than a decade of scientific discovery, preclinical, and clinical research conducted at leading hospitals, rehabilitation clinics, and neuroscience laboratories, the Company has developed ARC Therapy™, which has been awarded ten Breakthrough Device Designations from the US Food and Drug Administration (FDA).

ONWARD ARC Therapy, which can be delivered by external ARC-EX® or implantable ARC-IM® systems, is designed to deliver targeted, programmed spinal cord stimulation. Positive results were presented in 2023 from the Company's pivotal study, called Up-LIFT, evaluating the ability for transcutaneous ARC Therapy to improve upper extremity strength and function. The Company has submitted its regulatory application to the FDA for clearance of the ARC-EX System in the US and is preparing for regulatory submission in Europe. In parallel, the Company is conducting studies with its implantable ARC-IM Therapy, which demonstrated positive interim clinical outcomes for improved blood pressure regulation following SCI. Other ongoing studies include use of ARC-IM Therapy to address mobility after SCI and gait challenges in Parkinson's disease as well as using the ARC-BCI platform to restore thought-driven movement of both upper and lower limbs after SCI.

Headquartered in Eindhoven, the Netherlands, ONWARD Medical has a Science and Engineering Center in Lausanne, Switzerland and a US office in Boston, Massachusetts. The Company is listed on Euronext Brussels and Amsterdam (ticker: ONWD).

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